

REMARKS

Claims 1-16, 18-25, 31, and 32 are currently pending and stand rejected. Claim 12 is withdrawn. Applicants respectfully request reconsideration in view of the following remarks.

Claim Amendments

Applicants amend claims 1 and 5 to correct various informalities. No new matter is added.

Claim Objections

The Examiner objects to independent claim 1 because of the word “and” in line 9. Applicants amend claim 1 to obviate this objection. The Examiner also objects to dependent claims 6 and 7 as reciting “the angle” without proper antecedent basis. Applicants amend claim 5 to provide antecedent basis, thereby obviating the basis for the objection.

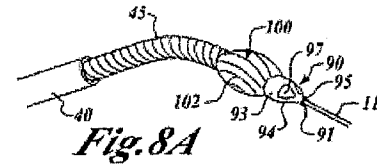
Rejections Pursuant to 35 U.S.C. § 102

Claims 1-4, 11, 13-16, 18, 21-25, and 31-32 are rejected pursuant to 35 U.S.C. §102(b) as being anticipated by U.S. Application No. 2002/0007190 of Wulfman et al. (“Wulfman”). Applicants respectfully disagree.

Claims 1

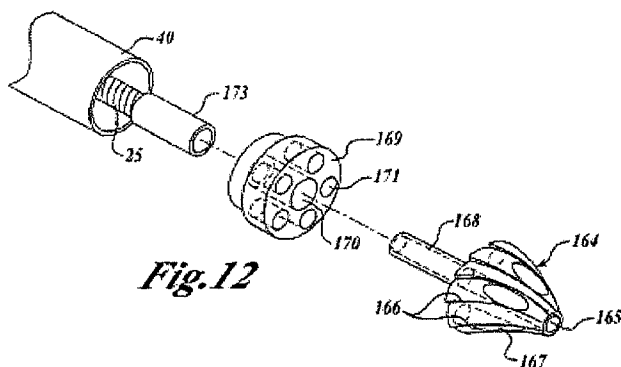
Independent claim 1 recites a tissue extraction and maceration device having a tissue harvesting tip formed on a distal end of a shaft that is effective to excise a tissue sample, a cutting member coupled to the shaft at a position proximal to the tissue harvesting tip that is effective to macerate a tissue sample excised by the tissue harvesting tip, and a sizing screen positioned proximal to the tissue harvesting tip and the cutting member. Wulfman is directed to an intraluminal material removal system using rotating cutting assemblies to remove tissue. The Examiner refers to FIG. 8A of Wulfman, which is reproduced herein, as teaching a tissue harvesting tip and cutting member as required by claim 1. In particular, the Examiner refers to

the distal cutter (90) as being the claimed tissue harvesting tip and the proximal cutter (100) as being the claimed cutting member. While these elements (90, 100) are both cutting members, they are not capable of meeting the requirements of claim 1. Claim 1 requires that the cutting member be effective to macerate a tissue sample *excised by the tissue harvesting tip*. As shown in FIG. 8A



and as taught by Wulfman, the distal cutter (90) cuts tissue which then enters a port (97) and travels into a lumen (46) (not shown) located inside the drive shaft (45). The cutting or abrading surfaces (102) of the proximal cutter (100) are formed on the *outside surface* of the cutter (100). *See para. [0097] of Wulfman*. Thus, there is no way for the proximal cutter (100) to macerate the tissue cut by the distal cutter (90). The tissue cut by the distal cutter (90) will travel within the lumen (45) without encountering any other cutting element, much less the abrading surfaces (102) located on the *outside* of the proximal cutter (100). Wulfman therefore cannot anticipate claim 1 because Wulfman fails to teach or suggest a cutting member positioned proximal to a tissue harvesting tip that is effective to macerate a tissue sample excised by the tissue harvesting tip.

In addition, the Examiner refers to the stationary bearing (169) in FIG. 12 of Wulfman, which is reproduced herein, as teaching the claimed sizing screen. There is no teaching or suggestion in Wulfman, however, that the stationary bearing (169) and bearing ports (171) would function as a sizing screen. In describing FIG. 12, Wulfman teaches that the device provides a “continuous passage for aspiration or infusion of fluids...[through]...cutter ports (167),



stationary bearing ports (171), and a lumen....” *See para. [0110] of Wulfman*. This indicates that the bearing ports (171) are not meant to restrain particulate, as would be the general function of a sizing screen, and instead are meant to allow a continuous flow of fluid and material. In addition, if the

stationary bearing *were* to restrain passage of material, the device would quickly become unusable because it would become clogged. Unlike Applicants' device which has a second cutting member effective to macerate and reduce the size of the tissue near the sizing screen, Wulfman has no such configuration. If the bearing ports (171) were to restrain passage of tissue, there is nothing to reduce the size of the tissue so it can eventually pass, and the device would become clogged and unusable. Thus, whatever is cut by the cutter (164) and enters ports (167) must also be able to pass through bearing ports (171). Accordingly, Wulfman cannot anticipate claim 1 because Wulfman fails to teach a sizing screen.

Futhermore, even if the Examiner defines the stationary bearing (169) to be a sizing screen, the additional requirements of claim 1 are not met because there is no teaching in Wulfman of an embodiment having a sizing screen positioned proximally to both a harvesting tip and a cutting member. Wulfman does not suggest that the embodiment shown in FIG. 12 and that shown in FIG. 8A could be combined. In addition, it is not clear how the two embodiments could structurally be combined. The stationary bearing (169) requires attachment to the base of a cutting member that is in the shape of a cone, as shown in FIG. 12, so that the size and profile of the tool remains constant as the fluid flows through the cutting member and into the bearing. The stationary bearing (169) cannot be attached to the base of a cutting member with a full ovular shape, such as the cutting member (100) shown in FIG. 8A, because the ovular cutting member (100) tapers to a reduced diameter portion at its base. This configuration would constrict fluid flow to the reduced diameter portion and prevent it from flowing through the ports (171) of the bearing, making the bearing useless and possibly even preventing fluid from flowing completely. In addition, there would be no reason to combine the distal cutting member (90) with the embodiment shown in FIG. 12 because the embodiment in FIG. 12 already has a ported cutting member. Wulfman never suggests the use of more than one ported cutting member in any embodiments because there is no reason to add a second ported cutting member to a device. Adding another ported cutting member to the embodiment in FIG. 12 would likely render the cutter (164) in FIG. 12 useless. Wulfman fails to teach or suggest an embodiment having the configuration of a sizing screen positioned proximally to a tissue harvesting tip and a cutting

members (254') do not have openings formed therein as required by claim 32, and instead are solid portions extending from the body of the attachment element. The ports (482) that the Examiner references are actually formed in the *body* of the attachment element and not in the *cutting members* (254'), as clearly shown in FIG. 24. Thus, Wulfman cannot anticipate claim 32 because Wulfman fails to teach or suggest a plurality of cutting teeth having openings formed therein.

In addition, claim 32 requires that the plurality of cutting teeth be effective to excise tissue samples and deliver the plurality of tissue samples to the inner lumen. The delivery of tissue to the inner lumen in Applicants' device is generally possible because of the openings formed *in* the plurality of cutting teeth. In this way, as soon as the tissue is excised by a cutting tooth, it is delivered through the opening in the tooth to the inner lumen. The attachment element of Wulfman shown in FIG. 24 would not be effective to accomplish such a thing because the ports (482) are not formed in the cutting members (254'). The ports (482) are positioned a distance away from the cutting members (254') on the body of the attachment element, they are generally small in size, and they are not aligned with the path tissue would likely follow when cut by the cutting member (254'). It is thus unlikely that the cutting members (254') would deliver the cut tissue to the ports (482) and into the interior of the attachment element. Accordingly, in addition to failing to teach the structure of claim 32, the attachment element of Wulfman is not capable of accomplishing a delivery of excised tissue as recited in the claim. For all of these reasons, claim 32 distinguishes over Wulfman and represents allowable subject matter.

Rejections Pursuant to 35 U.S.C. § 103

Wulfman and Wiley

Claims 5-9 are rejected pursuant to 35 U.S.C. §103(a) as being obvious over Wulfman in view of U.S. Patent No. 5,489,291 of Wiley. The Examiner argues that Wulfman discloses the invention substantially as claimed but fails to disclose certain requirements in claims 5-9. The Examiner thus relies on Wiley to teach these requirements. Wiley is directed to an apparatus for

removing tissue from a surgical site and does not remedy the deficiencies of Wulfman as to the requirements of claim 1, from which claims 5-9 depend. In particular, Wiley does not teach or suggest a cutting member positioned proximal to a tissue harvesting tip that is effective to macerate a tissue sample excised by the tissue harvesting tip. In addition, Wiley does not disclose a sizing screen. Accordingly, claims 5-9 distinguish over Wulfman in view of Wiley at least because they depend from an allowable base claim.

Wulfman

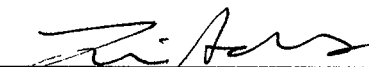
Claims 19-20 are rejected pursuant to 35 U.S.C. §103(a) as being obvious over Wulfman. As noted in detail above, independent claim 1, from which claims 19-20 depend, distinguishes over Wulfman and represents allowable subject matter. Accordingly, claims 19-20 distinguish over Wulfman at least because they depend from an allowable base claim.

Conclusion

Applicants submit that all claims are in condition for allowance, and allowance thereof is respectfully requested. The Examiner is encouraged to telephone the undersigned attorney for Applicants if such communication is deemed to expedite prosecution of this application.

Respectfully submitted,

Date: August 25, 2008



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